



Remarks

Claims 2 to 4, 24 to 26 and 28 have been cancelled without prejudice or disclaimer. Claims 1, 5 to 23, 27 and newly added claims 29 to 88 will be pending upon entry of this amendment.

Original claim 1 has been amended so as to recite only sequence identifiers when referring to disclosed nucleic and amino acid sequences of TR16. See, Paper No. 10, page 7. Support for these amendments is found in the specification at, for example, paragraphs [0014], [0022], [0025], [0030] and [0031]. Accordingly, no new matter has been added.

New claims 29 to 88 have been added in order to claim additional embodiments of the subject matter of the provisionally elected group. The claims are completely supported by the specification as originally filed and no new matter has been introduced.

Specifically, support for new claims 29-47 and 62-74 is found, for example, at paragraphs [0014], [0022], [0025] and [0029-0031]; while support for new claims 48 and 75 is found, for example, at paragraph [0044]; support for new claims 49-52 and 76-79 is found, for example, at paragraphs [0040-0041]; support for new claims 53 and 80 is found, for example, at paragraphs [0387] and [0494-0538]; and support for new claims 54, 55, 57-61, 81, 82, and 84-88 is found, for example, at paragraphs [0088-0100]. Therefore, no new matter has been added by way of amendment.

Restriction Requirement

The Examiner has required an election of the claimed subject matter under 35 U.S.C. § 121 of one of the following groups:

- I. Claims 1-19 and 27, in so far as they are drawn to polynucleotides of TR16, vectors, host cells and a method for producing a polypeptide recombinantly, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

- II. Claims 20, 26 and 28, drawn to TR16 polypeptides, classified in class 530, subclass 350.
- III. Claims 21 and 25, in so far as they are drawn to antibodies to TR16, classified in class 530, subclass 388.22, for example.
- IV. Claim 22, in so far as it is drawn to a method of treatment by administration of TR16 polypeptide, classified in class 514, subclass 2.
- V. Claim 22, in so far as it is drawn to a method of treatment by administration of an agonist of TR16 protein, classified in class 514, subclass 2.
- VI. Claims 23 and 24, drawn to a method of treatment by administration of an antagonist of TR16 protein, classified in class 514, subclass 2.

See, Paper No. 10, page 2. The Examiner contends that the inventions are distinct, each from the other.

In order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, the subject of group I as defined by the Examiner to include original claims 1-19 and 27, drawn to polynucleotides of TR16, vectors, host cells and a method for producing a polypeptide recombinantly, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example. Applicants reserve the right to file one or more divisional applications directed to non-elected subject matter should the restriction requirement be made final. In such case, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement.

As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the six (6) groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of multiple groups would entail a "serious burden." See M.P.E.P. § 803. In the present situation, no such showing has been made.

Applicants also respectfully point out that the Examiner has classified groups IV, V and VI in the same class and subclass (class 514, subclass 2), so that they have not acquired a separate status in the art, and would not present a serious burden to search and examine together.

Thus, in view of M.P.E.P. § 803, the claims of all of groups I-VI should be searched and examined in the subject application. Applicants submit that a search of the sequence of group I would provide useful information for the sequences of group II. Indeed, since groups I and II are directed to polynucleotides and the amino acid sequences they encode, a search of both of these groups would largely, if not entirely, overlap. Furthermore, since groups II and III are directed to amino acid sequences and antibodies they bind, a search of both of these groups would largely, if not entirely, overlap. Thus, since the searches for sequence of group I, polypeptide of group II, antibodies of group III and methods of treatment of groups IV, V and VI would overlap, the search and examination of all these groups would not entail a serious burden.

Further Restriction Within Group I.

The Examiner has required further restriction of the claimed subject matter within group I. In order to be fully responsive, Applicants hereby further provisionally elect, *with traverse*, within the subject matter of group I as defined by the Examiner, "a nucleic acid

comprising a polynucleotide encoding a TR16 protein (SEQ ID NOS:2 and 4).” *See*, Paper No. 10, page 4. Applicants reserve the right to file one or more divisional applications directed to non-elected subject matter should the restriction requirement be made final. In such case, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

The Examiner has further stated “**Applicant is advised that this is not a species election.**” *See*, Paper No. 10, page 6 (emphasis in original). Applicants respectfully disagree and traverse this interpretation and point out that each of the supposedly “patentably distinct nucleic acids” as identified by the Examiner corresponds to a species of the genus of epitopes as claimed in pending claim 9. Accordingly, Applicants respectfully contend that the Examiner’s requirement for further restriction within the subject matter of elected group I does indeed constitute a species election.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement. Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for the further restriction within the provisionally elected group I. The Examiner alleges that “[a]pplicants’ claims are drawn to numerous patentably distinct nucleic acid TR16 sequences.” *See*, Paper No. 10, page 4. Applicants note that the Examiner is requiring an election of groups of members of the Markush-type claims, Applicants respectfully point out that MPEP § 803.02 requires that “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits.” As described above, the members of the Markush groups of the pending claims to provisionally elected group I are sufficiently few in number and very closely related, as they are all different *portions of the TR16 polynucleotide sequence*, so that a search of all of the members may be made without a

serious burden, contrary to the Examiner's position. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that "[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability." If no prior art is found "that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended." *Id.* (emphasis added).

Further, Applicants point out that the Examiner has not addressed MPEP § 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), §803.04 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Applicants submit that the instant nucleic acids encode *different fragments of the same proteins*, rather than different proteins as contemplated by § 803.04. Section 803.04 further states that "nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." Thus, Applicants respectfully submit that the present requirement for further election within group I is improper. However, even if the Examiner contends that the instant nucleic acids encode different proteins within the scope of §803.04, Applicants submit that a reasonable number of such nucleic acids should be examined together, and the Examiner has given no indication why ten sequences are unreasonable in the present case.

Accordingly, Applicants respectfully request that the Restriction Requirement Under 35 U.S.C. § 121 and the further restriction within group II be withdrawn and the instant claims be examined in one application.

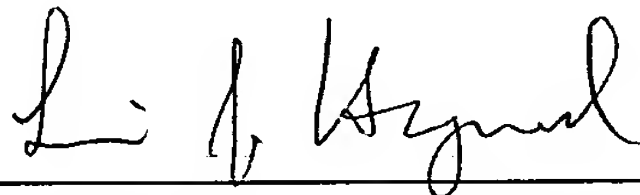
Conclusion

In view of the foregoing remarks, applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: April 10, 2003



Lin J. Hymel (Reg. No. 45,414)
Attorney for Applicants
Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
(301) 251-6015 (telephone)

KKH/LJH/BM
Enclosures